Endorsed by
ROYAL PHARMACEUTICAL SOCIETY

NPPG
Neonatal & Paediatric Pharmacy Group

Position statement

Labelling of Dispensed Oral Medicines for Children

Executive Summary

- Oral medicines are widely prescribed and dispensed for neonates and children.
- Parents, carers and patients are often reliant on dosing instructions provided on the dispensing label to ensure that the medicine is given correctly.
- The wording used to communicate dosing information on dispensing labels is known to be highly variable. This lack of consistency increases the potential for confusion and dosing error; such errors have been associated with patient harm, including death.
- There is limited evidence to inform the optimum approach, but continued variation is not in the interests of patient safety.
- To increase consistency and thus reduce the likelihood of error, it is recommended that when preparing dispensing labels for oral medicines:
    1. For **liquid medicines**, the **dose** is expressed **in millilitres (mL)** ***only***. The dispenser must also ensure that the volume specified can be measured with the administration device provided.
    2. For **solid dosage forms**, the **dose** is expressed **as the number of tablets or capsules to be taken.** The quantity of tablets to be taken must be expressed numerically rather than in words, e.g. “1 capsule” or “2 tablets” rather than “one capsule” or “two tablets”.
    3. The dosing **frequency** must be expressed in words as the number of times “a day” the medicine should be taken, rather than the number of times “daily” the medicine should be taken, e.g.: “ONCE a day”, “TWICE” a day, “THREE times a day” or “FOUR times a day”.

Background

Oral medicines are widely prescribed and dispensed for paediatric patients in both primary and secondary care settings. Parents, carers and patients are often reliant on dosing instructions provided on the dispensing label to ensure that the medicine is given correctly. Although there are regulatory requirements covering what information must be included on the dispensing label, there are no recommendations to specify how dosing instructions should be best worded to provide maximum clarity for paediatric patients and their caregivers. As a result, practice regarding the communication of dosing information is highly variable. Given that it is known that misunderstanding of medication instructions is common, the current inconsistency is likely to increase the potential for confusion and dosing error.

There is limited evidence to inform the optimum approach regarding communication of doses, however, continued variation is not in the interests of patient safety. The following standards have been developed to encourage consistent practice when labelling and dispensing medicines for children, and thus reduce risk of harm.

Recommendations

Labelling of Dosing Instructions for Liquid Medicines:

1) The Dose must be expressed numerically in millilitres ***only***.

a) The dose should not be expressed in mass or biological units (such as mg, micrograms, International Units).

b) The dose should not be expressed in "spoonfuls".

c) The dispenser must ensure that the dose volume specified can be measured with the administration device provided.

d) It may be necessary for the dispenser to round the dose volume to allow accurate measurement with the administration device provided. In general, dose volumes less than 1mL must be rounded to a maximum of two decimal places and dose volumes greater than 1mL should be rounded to a maximum of one decimal place.

2) Frequency must be expressed in words, as the number of times "a day" the medicine should be taken rather than the number of times "daily", e.g.: "ONCE a day", "TWICE" a day, "THREE times a day" or "FOUR times a day". In rare situations where more precise timing is needed, the time must also be given in words, e.g. "Every SIX hours", "Every FOUR to SIX hours".

Examples:

150mL Chlorphenamine 2mg/5mL solution
Take 2.5 mL FOUR times a day when required
A Child 15/04/2025
Keep out of reach and sight of children
Hospital Pharmacy, A Town, AB1 CD2. Tel: 020 123 4567

200mL Lactulose solution
Take 10mL TWICE a day
A Child 15/04/2025
Keep out of reach and sight of children
Hospital Pharmacy, A Town, AB1 CD2. Tel: 020 123 4567

Labelling of Tablets and Capsules, where the dose form is to be **swallowed whole**:

1) The Dose:

a) When the dose requires use of the entire tablet/capsule, it must be expressed numerically, and the type of solid dosage form should be included in the instruction, for example "1 capsule" or "2 tablets".

b) Where the dose requires use of a fraction of a tablet, the dose should be expressed in words and the type of solid dosage form should be included in the prescription, e.g. "half a tablet" or "one and a half tablets"

2) Frequency must be expressed as described under oral liquid dosing above.

Examples:

56 Levetiracetam 500mg tablets
Take 2 tablets TWICE a day
A Child 15/04/2025
Keep out of reach and sight of children
Hospital Pharmacy, A Town, AB1 CD2. Tel: 020 123 4567

21 Amoxicillin 250mg capsules
Take 1 capsule THREE times a day
A Child 15/04/2025
Keep out of reach and sight of children
Hospital Pharmacy, A Town, AB1 CD2. Tel: 020 123 4567

28 Atenolol 25mg tablets
Take half a tablet ONCE a day
A Child 15/04/2025
Keep out of reach and sight of children
Hospital Pharmacy, A Town, AB1 CD2. Tel: 020 123 4567

100 Paracetamol 500mg tablets
Take one and a half tablets FOUR times a day
A Child 15/04/2025
Keep out of reach and sight of children
Hospital Pharmacy, A Town, AB1 CD2. Tel: 020 123 4567

Recommendations continued

Labelling of Tablets and Capsules, where the tablet is to be **crushed and/or dispersed in water**, or capsule contents are to be mixed with water.

1) **The Dose** must be expressed numerically and the type of solid dosage form should be included in the instruction, for example "1 capsule" or "2 tablets".
2) A **volume of water** in which the tablet or capsule contents are to be dispersed should be expressed on the label. A standardised volume of 5mL is suitable in the majority of cases, and should be used wherever practical.
    - Where the required dose is less than the total tablet/capsule content, the volume of the prepared suspension/solution to be given should also be included on the label.
3) **Frequency** must be expressed as described under oral liquid dosing on page 2.

Examples:

28 Amlodipine 5mg tablets

Crush and disperse 1 tablet in 5mL water and take 4mL ONCE a day

A Child 15/04/2025

Keep out of reach and sight of children

Hospital Pharmacy, A Town, AB1 CD2. Tel: 020 123 4567

100 Gabapentin 300mg capsules

Empty and disperse the contents of 2 capsules in 5mL water and take 4mL THREE times a day

A Child 15/04/2025

Keep out of reach and sight of children

Hospital Pharmacy, A Town, AB1 CD2. Tel: 020 123 4567

Supporting Information

Oral medicines are commonly used in children. Dispensing of Oral Liquid Medicines (OLMs) can be particularly complex, with associated challenges of selecting an appropriate administration device and a need to round doses so that the volume to be given is measurable[1,2,3]. Children rely on parents/caregivers to administer medicines to them, and caregivers misreading or misinterpreting dosing instructions is frequently cited as a contributing factor in unintended paediatric dosing errors[4,5]. This is further compounded by the fact that written dosing instructions are typically more complex for children than for adults.

There are legal requirements governing the information which should be included on the dispensing label for each dispensed medicine, which include a need to provide "directions for use" of the medicine[6,7]. However, there are no agreed standards on the wording of dosing instructions and considerable variation is seen in practice. This publication provides clear guidance on how dosing instructions should be written, with a view to drive standardisation.

Variability in the Wording of Dosing Instructions

A 2022 survey of UK hospital pharmacy staff illustrated stark variation. Respondents (n=121) were asked to indicate the dosing instructions they would include on the label for 8 simulated prescriptions[8]. For each prescription, dosing instructions were worded in an average of 90 different ways (range: 80–120). When providing dosing instructions for solid dosage forms or sachets, 86.7% expressed the dose amount in words (e.g. one capsule), rather than numerals (e.g., 1 capsule). For OLMs, 65.7% expressed the dose amount in terms of 'mL', 30.1% as 'mL (mg)', and 4.3% as 'mg', 'mg (mL)', or 'mL (mL)' (e.g., 2 mL (two mL)). The amount of water suggested to enable "part-tablet" dosing from a 75 mg aspirin tablet ranged from 3-75mL.

Another 2022 study analysing the labelled dosing instructions on 210 community pharmacy-dispensed medicines belonging to patients admitted to a UK tertiary children's hospital showed similar variability[9]. The medicines had been dispensed in 70 different community pharmacies across 14 UK counties, representing 50 different independent and chain contractors. 36.2% of dosing instructions lacked an instruction verb (e.g. give, take). Twelve (5.7%) were considered ambiguous due to use of generic instructions (e.g. "as directed"); use of Latin dosing frequency abbreviations; or the absence of a dose quantity or unit of measurement. Nine (4.3%) dose instructions expressed the amount to give only in "mg" or 'mcg". Among the 129 dosing instructions stating a quantity of OLM to be administered, 55.8% were expressed as "…mL", 13.2% as "…mL (…mg)", 13.2% as "…mg (…mL)", and 11.6% as "…spoonful(s)". For medicines requiring 3 doses per day (n=57), 79% expressed the timing in frequency terms (e.g. "……three times per day") and 15.8% used explicit timings or intervals (e.g. "……at 8am, 2pm, 8pm").

Supporting Information continued

Standardisation of the Wording of Dosing Instructions Oral Medicines

At present, there is insufficient published evidence to inform how dosing instructions should be worded for optimal understanding. It is unlikely that there is a single best approach for all patients, parents and carers, however the current level of variability is far from ideal. Widespread adoption of standardised labelling, largely irrespective of the exact approach taken is likely to aid understanding and improve patient safety, even more so in individuals with lower literacy levels, a lower level of educational achievement and/or of non-white ethnicity, all of whom are more prone to misinterpreting dosing instructions[4].

Although not specific to paediatric practice, in 2021 the Australian Commission on Safety and Quality in Health Care published national labelling standards for dispensed medicines[10]. In relation to the wording of dosing instructions for solid dosage forms, this publication states that the dosing quantity should be expressed numerically, except in the case of fractions. Expressing fractions for solid dosage forms in numeric format (e.g. "½") or as decimals (e.g. "0.5") is prone to misinterpretation (e.g. "½" could be interpreted as "half" or "1 or 2". For oral liquids, it is advised the dose volume is displayed in numbers that relate to markings on the oral syringe, e.g. "0.5mL". Similarly, if an instruction includes a range, a word should be used between the numbers rather than a symbol e.g. '1 to 2' rather than '1-2' (which may be misinterpreted as 12). Finally, use of text which is ***all*** in capitals is considered harder to read, and so capital letters should be used judiciously.

The need to standardise paediatric dosing instructions to support comprehension and appropriate medicine use was further underscored by a 2024 survey of parent/carer preferences in relation to the wording of dose instructions[11]. The paper-based survey was distributed to parents/carers at 14 hospitals in England during their child's hospital visit. To assess preferences, participants were given a range of medication examples, and for each asked to select from a choice of two or four medicine labels which presented the same dosing instruction in different ways. Understanding of labelling for OLMs was also assessed by asking respondents to illustrate the amount they would give on a pictogram of a syringe.

250 respondents from 12 hospitals were included in the analysis. Preferences for OLM dose expression differed between individuals from healthcare and nonhealthcare backgrounds. 72.8% of those from non-healthcare backgrounds preferred "...mL" and 23.8% preferred "...mL (...mg)", compared to 46.9% and 40.6% of respondents from healthcare backgrounds respectively. Overall, 98.8%, 96.3% and 74.5% of the respondents marked the syringe images of OLMs correctly when doses were expressed as "…mL" , "…mL (…mg)" and "…mg (…mL)", respectively. A greater proportion of respondents from non-healthcare backgrounds preferred the numeric expression of "1 tablet" to "one tablet" (59.6% vs 33.3%). Regarding dose frequency expression, 51.6% preferred "Give 5mL twice a day" to "Give 5mL in the morning. Give 5mL in the evening", "Give 5mL in the morning and evening", or "Give 5mL two times a day". The most common theme identified in the open-ended question on preferences was the need for clearer and simpler instructions (23% of all respondents).

Provision of an Appropriate Administration Device for OLMs

Domestic teaspoons or measuring devices should not be used to administer OLMs due to a lack of consistent calibration of these products[1]. A 5mL medicine spoon or a 5mL oral/enteral syringe should be used to measure dose volumes which are 5mL or whole multiples of 5mL; the choice of device should take into account patient and parent/carer preferences[1]. Where the dose volume is not 5mL or a whole multiple of 5mL, an appropriate oral/enteral syringe should be used. Where the dose volume is less than 1mL, a 1mL syringe should be used to minimise dosing inaccuracy. Use of larger syringes to measure these smaller volumes results in a greater degree of inaccuracy and variability, even if the required volume corresponds with the available graduations[3].

In some cases, it may be necessary to round the required dose volume to enable accurate measurement. For low-risk medicines, clinically acceptable dosing variance is generally considered to be up to 10% of the intended dose; for high-risk drugs, a variance up to 5% of is acceptable[12].

Importance of Ensuring Parent/Carer Understanding

In addition to ensuring the use of clear, standardised wording on dispensing labels, it is important that patients, parents and/or carers are given verbal instructions as to how the medicine should be used. The dispenser should also ensure patient, parent/carer understanding of the information given, including providing support with/demonstration of the use of administration devices[6]. It has been shown that provision of an appropriate administration device coupled with support in using the device correctly decreases the risk of medication error[13,14.]

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Disclaimer

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